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36234 7590 07/23/2008

THE MCCALLUM LAW FIRM, P. C.
685 BRIGGS STREET
PO BOX 929
ERIE, CO 80516

EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 07/23/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,237	08/04/2006	Kerry Michelle Dunse	007193-13	1348
TITLE OF INVENTION: INSECT CHYMOTRYPSIN AND INHIBITORS THEREOF				

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	10/23/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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36234 7590 07/23/2008

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,237	08/04/2006	Kerry Michelle Dunse	007193-13	1348

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APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	10/23/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
MOORE, WILLIAM W	1656	530-370000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

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☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.**

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36234	7590	07/23/2008	EXAMINER	
THE MCCALLUM LAW FIRM, P. C. 685 BRIGGS STREET PO BOX 929 ERIE, CO 80516			MOORE, WILLIAM W	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 07/23/2008

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 112 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 112 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

10/554,237

Examiner

WILLIAM W. MOORE

Applicant(s)

DUNSE ET AL.

Art Unit

1656

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the election made 18 April 2008 and the interview conducted 2 July 2008.
2. ☒ The allowed claim(s) is/are 68-86.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 20070316 & 20070412
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Amend the two paragraphs at page 84, lines 2-19, of the specification thus:

The cDNA clones were grouped on the basis of restriction fragment patterns obtained using combinations of the endonucleases *Bam*HI, *Xho*II, *Kpn*I, *Sac*I, *Sac*II, and *Sal*I (Promega). RT-PCR products and cDNA inserts were sequenced in both directions using M13 universal primers at either Micromon sequencing facility at Monash University (Melbourne) or SUPAMAC at the Royal Prince Alfred Hospital in Sydney. The sequence data was edited using the BioEdit v5.0.9.1 software written by Tom Hall, North Carolina State University freely available at the web address: mbio.ncsu.edu/BioEdit/bioedit ~~www.mbio.ncsu.edu/BioEdit/bioedit.html~~. Sequence homologies were assessed using the BLASTN search facility at National Centre for Biotechnology Information (NCBI) and further multiple sequence alignments were performed using ClustalW version 1.4. at the Network Protein Sequence Analysis facility (NPSA; http://npsa-pbil.ibcp.fr/cgi-bin/align_clustalw.pl) (Combet *et al.*, *TIBS*. **25**: 147-150, 2000).

The web based program 'PSORT II' available at the Human Genome Centre at the University of Tokyo (<http://psort.nibb.ac.jp/form2.html>), was used to predict signal peptide cleavage points. UTRscan was used to detect functional elements in the 3' untranslated regions of the cDNA clones [Pesole, *Trends Genet.* **15**: 378, 1999]. (<http://biggestarea.be.enr.it/BIG/UTRscan/>).

Amend the paragraph at page 85, lines 9-25, of the specification thus:

The deduced amino acid sequences from the cDNA clones HpF2B (sensitive) and HpF5 (insensitive) were modeled on the structures of the *Bos taurus* (bovine) and fire ant chymotrypsins, obtained from the Research Collaboratory for Structural Bioinformatics (RCSB) Protein Data Bank site (<http://www.rcsb.org/pdb/>). The *Helicoverpa* chymotrypsins are predicted to adopt similar structures to those reported for all the chymotrypsin structures available in the PDB databank. The modeled structure consists of the classic serine protease fold consisting of two, six-stranded anti-parallel β barrels with the catalytic triad located between the two domains. Two surface loops, 60 and 142 are considerably larger in the *H. punctigera* chymotrypsins (Figures 15 and 16). Due to the limitations of modelling, a small amount of ambiguity was present in several surface loops, some of which are cleaved in mammalian chymotrypsins (loop 142), but remain intact within insect chymotrypsins. The only reported crystal structure of an insect chymotrypsin is from the fire ant, *Soenopsis invicta* (Botos *et al.*, *Journal of Molecular Biology* **298**: 895-901, 2000) and this was used to help refine the orientation of the surface loops on the model of the *Helicoverpa* chymotrypsin.

To assist the printer, the non-amended claims 70 and 71 presented by Applicant in the amendment filed 18 April 2008 are reproduced following the amended claim 69 with the designation "Previously presented".

Cancel claims 27-51 and 55-68.

Amend claim 69 thus:

69. (Amended) An antagonist that comprises an amino acid sequence having at least 90% amino acid sequence identity to the amino acid sequence set forth in SEQ ID NO:81 and that inhibits the proteolytic activity of the ~~a~~ protein having the ~~an~~ amino acid sequence set forth in ~~selected from the group consisting of SEQ ID NO:2[[,]] wherein said protein exhibits resistance to a protease inhibitor (PI) from *Nicotiana glauca*, and wherein said antagonist comprises the amino acid sequence set forth in SEQ ID NO:81 or an amino acid sequence having at least 90% amino acid sequence identity thereto.~~
70. (Previously presented) The antagonist of Claim 69 wherein said antagonist comprises the amino acid sequence set forth in SEQ ID NO:81.

71. (Previously presented) A composition comprising an antagonist of Claim 69.

Add the new claims 72-83:

72. (New) The antagonist of Claim 69 wherein said antagonist comprises an amino acid sequence having at least 95% amino acid sequence identity to the amino acid sequence set forth in SEQ ID NO:81.
73. (New) A composition comprising the antagonist of Claim 72.
74. (New) A composition comprising the antagonist of Claim 70.
75. (New) An isolated nucleic acid molecule having a sequence encoding the antagonist amino acid sequence according to claim 69.
76. (New) The isolated nucleic acid molecule of claim 75, wherein the antagonist comprises an amino acid sequence with at least 95% sequence identity to the amino acid sequence set forth in SEQ ID NO:81.
77. (New) The isolated nucleic acid molecule of claim 75, wherein the antagonist comprises the amino acid sequence set forth in SEQ ID NO:81.
78. (New) A vector comprising the antagonist-encoding nucleic acid sequence according to claim 75.
79. (New) A vector comprising the antagonist-encoding nucleic acid sequence according to claim 76.
80. (New) A vector comprising the antagonist-encoding nucleic acid sequence according to claim 77.

81. (New) An isolated genetically modified cell comprising a nucleic acid molecule having a sequence encoding an amino acid sequence having at least 90% amino acid sequence identity to the amino acid sequence set forth in SEQ ID NO:81 and that inhibits the proteolytic activity of the protein having the amino acid sequence set forth in SEQ ID NO:2.
82. (New) An isolated genetically modified cell comprising a nucleic acid molecule having a sequence encoding an amino acid sequence having at least 95% amino acid sequence identity to the amino acid sequence set forth in SEQ ID NO:81 and that inhibits the proteolytic activity of the protein having the amino acid sequence set forth in SEQ ID NO:2.
83. (New) An isolated genetically modified cell comprising a nucleic acid molecule having a sequence encoding the amino acid sequence set forth in SEQ ID NO:81.
84. (New) The isolated cell of claim 81 which is a genetically modified plant cell.
85. (New) The isolated cell of claim 82 which is a genetically modified plant cell.
86. (New) The isolated cell of claim 83 which is a genetically modified plant cell.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Donna M. Ferber on 7 July 2008.

The following is an examiner's statement of reasons for allowance:

The non-elected claims are canceled in the above amendment and claim 69 is amended to clarify its intended subject matter. The teachings of the specification at page 24, lines 1-5, page 47, lines 14-19, page 48, lines 19-31, page 93, lines 1-15 and Figure 26, pertaining to the StPotIa inhibitor, and the teachings of Beuning et al., 1994, made of record with Applicant's IDS, at pages 647-652, including their alignment of inhibitor amino acid sequences in Table 2 at page 648, demonstrate the state of the art at the time the invention was made. The teachings of Beuning et al. show (i) that one of skill in the art would readily identify the P₁₀ through P₈ positions of the active site loop within SEQ ID NO:81¹ wherein the relatively non-conservative substitutions of proline at the P₁ position of the protease-binding loop, where alanine or threonine occur in other potato PI inhibitors, and alanine at the P₋₁ position of the protease binding loop, where methionine or leucine occur in other potato PI inhibitors, are likely to contribute to the particular affinity of the inhibitor for the protease of SEQ ID NO:2 and (ii) that such an artisan would be well aware of the need for conserving the two cysteines, as well as the PI family I "signature" structural motif,² in modifying SEQ NO:81, where fourteen other positions, including the P9 position are shown by Beuning et al. to be variable in other potato PI

¹ Positions 78-95 of SEQ ID NO:81.

² Positions 51-63 of SEQ ID NO:81.

inhibitors' carboxyl-proximal regions and Beuning et al. teach that the amino-proximal region of these protease inhibitors may be truncated in part without affecting protease inhibitory activity. Where the specification both discloses four structurally similar species of inhibitors – in SEQ IDs NOs: 77, 78, 80, and 82 – and the prior art discloses still other similar inhibitors sharing as much as 79% identity with SEQ ID NO:81, and discloses an assay that particularly identifies inhibitors of the proteolytic activity of SEQ ID NO:2, the teachings of the specification and the prior art are adequate to support the alteration of as many as eleven amino acid positions in SEQ ID NO:81. The new claims 72-86 describe subject matter supported by the disclosures at, *inter alia*, page 58, lines 20-31, and page 62, lines 22-28, of the specification.

The priority date for the disclosure of SEQ ID NO:81 herein is the 23 April 2003 filing date of the parent application 60/465,054. The prior art made of record herewith does not disclose or suggest the discovery or preparation of a protease inhibitor, i.e., an antagonist, having an amino acid sequence that shares 90% sequence identity with SEQ ID NO:81 herein, nor does it disclose a polynucleotide encoding such an inhibitor, a vector comprising or an encoded amino acid sequence, that has 90% sequence identity with amino acid sequence set forth in SEQ ID NO:81. Thus claims 69-86 are allowed herewith.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general

Art Unit: 1652

nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/Nashaat T. Nashed/
Nashaat T. Nashed, Ph.D.
Supervisory Primary Examiner
Art Unit 1652

/William W. Moore/
William W. Moore
7 July 2008